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| APPLICATION NO. FILING DATE    |                       | NG DATE    | FIRST NAMED INVENTOR    | ATTORNEY DOCKET NO.    | CONFIRMATION NO. |  |
|--------------------------------|-----------------------|------------|-------------------------|------------------------|------------------|--|
| 09/901,310                     | 09/901,310 07/09/2001 |            | Alfred S. Despres III   | HAYES-707 CON          | 8573             |  |
| 75                             | 590                   | 10/03/2002 |                         |                        |                  |  |
| Pandiscio & P                  |                       | )          | EXAMINER                |                        |                  |  |
| 470 Totten Pon-<br>Waltham, MA |                       |            |                         | JACKSON, SUZETTE JAMIE |                  |  |
|                                |                       |            |                         | ART UNIT               | PAPER NUMBER     |  |
|                                |                       |            |                         | 3738                   |                  |  |
|                                |                       |            | DATE MAILED: 10/03/2002 |                        |                  |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   |   | Application No. Applicant(s) |       | Applicant(s)                                       |  |  |  |  |
|---|---|------------------------------|-------|--|--|--|--|--|
|   |   | 09/901,310                   |       | DESPRES ET AL.                                     |  |  |  |  |
|   | Office Action Summary   | Examiner                     |       | Art Unit   |  |  |  |  |
|   |   | Jackson J Suzet              | te    | 3738   |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  |   |                              |       |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status |   |                              |       |  |  |  |  |  |
| 1) 🗆  | Responsive to communication(s) filed on   | •                            |       |  |  |  |  |  |
| 2a)□  | This action is <b>FINAL</b> . 2b)⊠ TI   | nis action is non-f          | inal. |  |  |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims   |   |                              |       |  |  |  |  |  |
| 4) 🖂  | Claim(s) 1-75 is/are pending in the application   | n.                           |       |  |  |  |  |  |
| ,   | 4a) Of the above claim(s) <u>55-75</u> is/are withdrawn from consideration.   |                              |       |  |  |  |  |  |
| 5)□   | 5) Claim(s) is/are allowed.   |                              |       |  |  |  |  |  |
| 6) 🗆  | 6)  Claim(s) <u>1-10,12-28,30-46 and 48-54</u> is/are rejected.   |                              |       |  |  |  |  |  |
| 7) 🖂  | Claim(s) <u>11,29 and 47</u> is/are objected to.  |                              |       |  |  |  |  |  |
| 8)□   | 8) Claim(s) are subject to restriction and/or election requirement.   |                              |       |  |  |  |  |  |
| Applicati   | Application Papers  |                              |       |  |  |  |  |  |
| 9) The specification is objected to by the Examiner.  |   |                              |       |  |  |  |  |  |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.   |   |                              |       |  |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |   |                              |       |  |  |  |  |  |
| 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.  |   |                              |       |  |  |  |  |  |
| If approved, corrected drawings are required in reply to this Office action.  |   |                              |       |  |  |  |  |  |
| 12)☐ The oath or declaration is objected to by the Examiner.  |   |                              |       |  |  |  |  |  |
| Priority under 35 U.S.C. §§ 119 and 120   |   |                              |       |  |  |  |  |  |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).   |   |                              |       |  |  |  |  |  |
| a) All b) Some * c) None of:  |   |                              |       |  |  |  |  |  |
| 1. Certified copies of the priority documents have been received.   |   |                              |       |  |  |  |  |  |
|   | 2. Certified copies of the priority documents have been received in Application No  |                              |       |  |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.  |   |                              |       |  |  |  |  |  |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  |   |                              |       |  |  |  |  |  |
| a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.   |   |                              |       |  |  |  |  |  |
| Attachment(s)   |   |                              |       |  |  |  |  |  |
| 2) Notic  | e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s) | 4)<br>5)<br>6)               |       | (PTO-413) Paper No(s) Patent Application (PTO-152) |  |  |  |  |
| U.S. Patent and T   | ademark Office  |                              |       |  |  |  |  |  |

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# **DETAILED ACTION**

### Election/Restrictions

1. Applicant's election without traverse of 9/16/02. Claims 55-75 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group II, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 6.

# Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.
- The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).
- 4. Claims 1-3, 6, 8, 10, 13, 16-21, 24, 26-28, 31, 34-39, 42, 44-46, 49, 52-54 rejected under 35 U.S.C. 102(e) as being anticipated by Buechel et al.5,702,448 which discloses a metallic implant (10), but not limited to any particular implant; a metallic alloy substrate (20) made of

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titanium alloy such as titanium aluminum vanadium alloy (col. 6. lines 40-42); or cobalt-chromium alloys; the implant provided with a porous coating (22) which may be the same alloy as the substrate or separately applied thereto. In other embodiments the macro surface treatment may be defined by a mesh defining a textured or otherwise irregular surface area that will promote in-growth (col. 7, lines1-10). The implant further includes a hard wear resistance coating (26) applied by thin film coating methods (col. 8, lines 50-54, coating materials col. 5 lines 13-16). See Figures 1-3.

# Claim Rejections - 35 USC § 103

- 5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 6. Claims 2-5, 20-23, and 38-41 rejected under 35 U.S.C. 103(a) as being unpatentable over Buechel et al. in view of Homsy 5,176,712. Buechel et al. has been disclosed above noting figure 1, however Buechel does not disclose a coating that is softer then the structured surfaces or softer than the structured substrate. Homsy teaches an endoprosthesis where at least a portion of the proximal surface is biocompatible, porous, deformable and allows for tissue-growth promoting and another portion of the proximal surface is biocompatible, porous non-deformable and tissue in-growth promoting thus making the biocompatible coating more biocompatible than the substrate. (See col. 2, line 8-12 and col. 5, lines 47-51 figures 10c). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coating

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materials and/or amounts to supply softer coatings to further allow for tissue in-growth and/or on growth to make the prosthesis adhere to the patients remaining tissue.

- 7. Claims 7-9, 14, 25-27, 32, 43-45 and 50 rejected under 35 U.S.C. 103(a) as being unpatentable over Buechel et al. in view of Lemelson et al. 6,083,570. Buechel et al. has been disclosed above however Buechel et al. does not specify applying a coating by utilizing chemical vapor deposition or physical vapor deposition. Lemelson et al. teaches applying coatings to substrates by these techniques have been utilized (see col. 1, lines 32-34 and col. 2, lines 35-36) and that multiple-layered coatings have been applied to substrates (col. 4, lines 5-6). It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize deposition techniques and multiple layers of coating because it would allow for greater adherence of certain coatings to certain metals and more wear resistant prosthesis.
- 8. Claims 12, 15, 30, 33, 48 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buechel et al. in view of Arpac et al. Buechel et al. has been disclosed however does not specify nano layers. Arpac teaches substrate coatings which utilize nano particles to for layers (see col. 7, lines 61-67 and col. 12, line 12). It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize nano layers in order to provide a material which evenly distributed coating substrate applications.

#### Allowable Subject Matter

Claims 11, 29 and 47 objected to as being dependent upon a rejected base claim, but 9. would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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## **Double Patenting**

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-54 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 6,261,322. Although the conflicting claims are not identical, they are not patentably distinct from each other because Patent '322 discloses and claims the same subject matter in a narrower manner. Application 09/901,310 restates the coated substrate prosthesis in broad terminology.

#### Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hunter et al. 6,447,550; Neerinck et al. 6,228,471; Dearnaley et al. 6,171,343; Lemelson et al. 6,165,616; Li 6,139,585; Pope et al. 6,010,533; Devlin et al. 5,981,827; Davidson et al. 5,545,227; Mastrorio et al. 5,746,272; Bobyn 4,978,358 all show related material.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 703-308-6516.

- 14. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3580.
- 15. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

S. Jackson

27 September 2002

David H. Willse Primary Examiner Page 6